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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,990	07/28/2003	Dietrich Wilhelm Schacht	25352	4266

20529 7590 09/05/2006

NATH & ASSOCIATES
112 South West Street
Alexandria, VA 22314

EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/627,990

Applicant(s)

SCHACHT ET AL.

Examiner

Konata M. George

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/8/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-14 are pending in this application.

Drawings

1. The drawing(s) filed under 37 CFR 1.184 or 1.152 are accepted by the examiner.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on October 8, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97.

Accordingly, the examiner has considered the information disclosure statement.

Claim Objections

3. Claims 1-12 are objected to because of the following informalities: Claims 1-12 contain the language "characterized in that", please rephrase the language to read "wherein".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

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1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 2, 5-7 and 10-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 10/623,864. Although the conflicting claims are not identical, they are not patentably distinct from each other because both copending applicants are directed towards a transdermal delivery system comprising a backing layer, a self-adhesive matrix containing a drug and a protective foil or sheet. The difference between the two applications is that in claim 1 of the instant application ('990) the drug is the broad category of amine-functional drugs and the drug of the copending application ('864) is specific to rotigotine. However, depending claims 5-7 of the instant application ('990) discloses that rotigotine is a suitable drug to be used in the system and thus is obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 11-13, the phrase "type" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "type"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni (US 3,797,494) in view of Lee et al. (US 5,500,222), Klose et al. (US 2004/0013620), Colley et al. (US 5,217,718) and Goodman and Gilmans (1990).

Applicants claim a transdermal delivery system (TDS) comprising a backing layer, a self-adhesive matrix containing a drug and a protective foil or sheet, wherein the matrix contains the drug in microreservoirs.

Determination of the scope and content of the prior art

(MPEP §2141.01)

Zaffaroni discloses in figures 1-5, specifically figures 4 and 5 an adhesive bandage having a backing layer and microcapsules of drug distributed throughout the adhesive layer (col. 9, lines 54-62). Column 10, lines 32-34 teach that the microcapsules have an average particles size from several tenths of a micron to 5,000 microns. Column 12, lines 9-67 described the various drug classes, which can be employed in the transdermal system. Column 14, line 60 through column 15, lines 20 teach examples of adhesives which may be employed in the system of which a silicone-type i.e. silicone rubber is taught. Column 15, lines 58-65 teach applying the bandage to the affected area of the patients skin.

Lee et al. discloses that oxybutynin can be administered via a transdermal delivery system.

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Klose et al. teaches a transdermal delivery of antiParkinsons agents wherein rotigotine is disclosed (paragraph [0026]).

Colley et al. discloses a transdermal delivery device wherein the pressure adhesive can be polysiloxanes, silicones, polyacrylates, etc. or mixtures thereof (col. 6, lines 20-38).

Goodman and Gilmans teach that tertiary amines such as oxybutynin can be used for their antispasmodic properties (page 160).

Ascertainment of the difference between the prior art and the claims

(MPEP §2141.02)

The prior art reference of Zaffaroni does not teach the log p or the pKa values of the amine-functional drug or the specific drugs as claimed. It is not taught by Zaffaroni the matrix comprising two or more silicone adhesives.

Finding of prima facie obviousness

Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Lee et al., Klose et al., Colley et al. and Goodman and Gilmans with Zaffaroni to disclose the claimed invention. Column 14, lines 60-62 teach that any well-known dermatologically acceptable pressure sensitive adhesives can be used in the claimed system. One of ordinary skill in the art could used the teachings of Colley et al. describing the use of silicones or mixtures thereof as

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the adhesive when formulating the TDS of the instant invention to optimize the performance of the drug-adhesive matrix. Zaffaroni et al. discloses in column 12, line 38 the use of antispasmodic agents in the TDS. Goodman and Gilman's is being relied upon to teach that oxybutynin can be used as an antispasmodic agent, and since Zaffaroni teaches the broad category of antispasmodic agents the use of oxybutynin would have been obvious to one of ordinary skill in the art. Although, the prior art mentions atropine, methscopolamine, etc. in the reference it is only a small representation of the broad category. Lee et al. is being relied upon to teach that oxybutynin can be delivered via a TDS. Klose et al. is being relied upon to teach that rotigotine can be administered via transdermal delivery. One of ordinary skill in the art would be motivated to incorporate an antiParkinson agent into a TDS for the purposes of providing a sustained release of the agent to the patient in need thereof. With respect to the claimed log p or the pKa values of the amine-functional drug, absent a clear showing of criticality, the determination of the particular log p or the pKa values of the amine-functional drug is within the skill of the ordinary worker as part of the process of normal optimization to achieve the desired results of the claimed composition.

Conclusion

7. Claims 1-14 are rejected.

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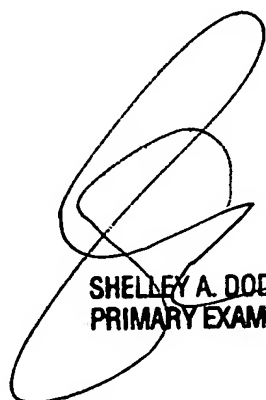
Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER